K123612

5 510(k) Summary

JAN 17 2013

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter:
Fujirebio Diagnostics, Inc.
940 Crossroads Blvd
Seguin, TX 78155
(830) 372-1391 ex. 210
Establishment Registration Number: 1643621

Contact Person: Kent Pruett

Device Name: FDI Glucose Control Solution for use with Accu-Chek Aviva

Common Name: Single Analyte Control Solution, All Types (Assayed and Unassayed)

Classification Name: Quality Control Material (assayed and unassayed).

Classification: Class I, per 21 CFR 862.1660
Reserved

Product Code: 75 JJX

Panel: Chemistry

Predicate Devices:

Name:	ACCU-CHEK Aviva Control Level 1
Manufacturer:	Roche Diagnostics
510(k) No.:	k043474

Device Description: The FDI Glucose Control Solution for Aviva consists of a viscosity-adjusted, aqueous liquid control solution containing a known quantity of glucose. The product is packaged in plastic dropper tipped bottles for easy application of the control solutions to the test strips and a red coloration to aid the user to visually confirm application of the control. The product is non-hazardous and contains no human or animal derived materials.

Intended Use: The FDI Glucose Control Solution is intended for use with Aviva Plus test strip when used on the Accu-Chek® Aviva blood glucose meter. The control

solution is used with the Aviva Plus test strips to check that the meter and test strips are working together properly.

Comparison to Predicate Devices:

Characteristic/ Aspect	Predicate Device No. 1	New Product
Name	ACCU-CHEK Aviva Control Level 1	FDI Glucose Control Solution for Accu-Chek Aviva
510(k), Date	K043474 04/27/2005	
Number of Levels	1	1
Analyte	Glucose	Glucose
Target Range (mg/dL)	25 – 55[2]	23 – 53[1]
Container	Plastic bottle with dropper-tip	Plastic bottle with dropper-tip
Fill Volume	2.5 mL	3.6 mL
Color	Blue	Red
Matrix	Glucose, buffer, salts, non-reactive ingredients, preservative, FD & C Blue #1	Water, D-Glucose, a viscosity modifier, buffer, salt, preservatives, and FD&C Red #40
Indications for Use	Checks that the meter and test strips are working properly to give reliable results.	The FDI Glucose Control Solution is intended for use with Aviva Plus test strip when used on the Accu-Chek® Aviva blood glucose meter. The control solution is used with the Aviva Plus test strips to check that the meter and test strips are working together properly.
Target Population	Professional and home use	Professional and home use

[1]Based on a +/- 5% glucose concentration variability lot-to-lot and +/- 15 mg/dl range
[2]Derived from the control ranges assigned by the manufacturer

Performance Studies: Tests were performed to verify specific performance characteristics:

Real Time Stability: Samples were periodically removed and tested in triplicate on a commercially available clinical chemistry analyzer. The study supports a shelf life of 24 months when stored at 15-30°C.

Open Vial Stability: A number of test and control vials were evaluated for 13 weeks. Each day all vials were opened, allowed to stand for ten minutes, then closed and stored at room temperature. Each week one test group vial was assayed and one control group vial was assayed in triplicate using the ACE Glucose assay. The Control vial was opened on the date of performing the assay and then discarded after testing was complete. The study supports the claimed open vial stability of 90 days when stored at 15 - 30°C.

Test Precision: Studies performed per **CLSI *Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline*** – Second Edition. CLSI document EP5-A2; 2004. No precision claims will be made for this product.

Value Assignment: The control solutions are analyzed using a single AVIVA monitor using three different lots of test strips, 10 replicates per strip lot, over three days. Acceptable ranges are based on pre-determined acceptance criteria established by the manufacturer for glucose recovery for each lot. The glucose control value ranges are lot dependent; therefore the range for each lot is printed on the control solution vial label.

Traceability: The control is traceable to an in-house 45 mg/dL Standard traceable to the NIST Standard Reference Material 917b. The in-house 45 mg/dL Standard is produced using SRM917.

Conclusion: Comparison of the performance characteristics, formulation and intended use support the claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

January 17, 2012

Fujirebio Diagnostics, Inc.
c/o Kent Pruett
940 Crossroads Blvd.
Seguin, TX 78155

Re: k123612
Trade/Device Name: FDI Glucose Control Solution for use with Accu-Chek Aviva
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (assayed and unassayed)
Regulatory Class: I, reserved
Product Code: JJX
Dated: November 23, 2012
Received: December 20, 2012

Dear Mr. Pruett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Ruth A. Chesler

Courtney H. Lias, Ph.D
Director, Division of Chemistry and Toxicology
Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k123612

Device Name: FDI Glucose Control Solution for use with Accu-Chek Aviva

Indications For Use: The FDI Glucose Control Solution is intended for use with Aviva Plus test strip when used on the Accu-Chek® Aviva blood glucose meter. The control solution is used with the Aviva Plus test strips to check that the meter and test strips are working together properly.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X__ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Katherine Serrano
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Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)